

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing (day/month/year) **See form PCT/ISA/210**

Applicant's or agent's file reference

I60083PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/DE2005/000233

International filing date (day/month/year)

10.02.2005

Priority date (day/month/year)

10.02.2004

International Patent Classification (IPC) or both national classification and IPC

A61B17/56, A61B5/00, A61F2/30

Applicant

CHARITÉ-UNIVERSITÄTSMEDIZIN BERLIN

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP

Authorized officer

Facsimile No.

Telephone No.

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Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amine acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. IV

Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☒ paid additional fees
 - ☐ paid additional fees under protest
 - ☐ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:

See supplemental sheet

4. Consequently, this opinion has been established in respect of the following parts of the international applications
- ☒ all parts
 - ☐ the parts relating to claims Nos. _____

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability:
citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	20	YES
	Claims	1-6, 7-12, 13-19	NO
Inventive step (IS)	Claims	20	YES
	Claims	-	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	-	NO

2. Citations and explanations:

1 Reference is made to the following documents:

D1: WO 01/49173 A
D2: US 6 034 296 A
D3: US 4 186 749 A
D4: US 2002/151770 A1
D5: US 6 464 687 B1
D6: WO 01/19239 A
D7: DE 100 48 375 A1
D8: US-A-5 769 893

GROUP 1

2 Novelty of claims 1-6 and 17-19 and inventive step
of claims 13-15 in respect of D1

2.1 Claim 1:

The present application does not meet the requirements of PCT Article 33(1), because the subject matter of claim 1 is not novel within the meaning of PCT Article 33(2).

Document D1 discloses (the references between parentheses relate to said document): A component

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(see figure 1: probe 1) suitable for arranging on an implant (see figures 5 and 7B), with:

- a base component (housing 37);
- at least one sensor device (pressure sensor 8) which is arranged in the base component and is used to detect a measurement variable and to produce measurement data for the detected measurement variable (page 4, lines 21-27);
- a telemetry device (electronic circuit 14 and coil 13) which is arranged in the base component and is used to emit and/or receive data; and
- a data transfer connection (electric conductor 15) which is arranged between the at least one sensor device and the telemetry device (page 4, lines 17-18) for the purpose of transferring data between the at least one sensor device and the telemetry device, said data comprising the measurement data (see also page 4, lines 23-28).

The claim is worded in such a way that even the "stem 11" can be regarded as an assembly means, because it permits the assembly (see figure 5). The "bone screw 29" (figure 6) and the holes provided for it also represent assembly means.

2.2 Claims 2 and 3: The term "assembly section" does not represent a further restriction of the scope of protection.

The "bone screw 29" (figures 5 and 6) has a threaded section.

2.3 Claims 4-6: The base component is T-shaped (see

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figure 1, page 14, line 14) and the telemetry device
(13, 14) is situated in a head part.

2.4 Claims 17-19: Figure 7B of D1 discloses a
replacement implant that has a recess for the
component.

2.5 The present application does not meet the
requirements of PCT Article 33(1), because the
subject matter of these claims is not novel within
the meaning of PCT Article 33(2).

2.6 Claims 13-15: It would be obvious for a person
skilled in the art to use the same arrangement as in
figure 7B for a support implant. Therefore, the
subject matter of claims 13-15 is not inventive (PCT
Article 33(3)).

3 Novelty of claims 1-3, 5, 13 and inventive step of
claims 4, 14, 15 and 17-19 in respect of D2

3.1 Claims 1-3: Document D2 discloses, in figures 1 and
3, a base component (encasement 68), a sensor (20,
62) and a telemetry device (telemetry unit 40, 64,
column 4, lines 10-11). A connection between these
is an implicit feature. The "metal substrate 78"
(figure 6) and the "screw 82" represent assembly
means.

3.3 Claim 5: Figure 6 shows a sensor (62) in the area of
an end (the left end in the picture), and a
telemetry device lying opposite it.

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3.4 Claim 13: Figure 6 of D1 discloses a support implant with a device according to claim 1.

3.5 The present application does not meet the requirements of PCT Article 33(1), because the subject matter of these claims is not novel within the meaning of PCT Article 33(2).

3.6 Claim 4: The subject matter of this claim does not involve an inventive step since, in its present wording, it relates merely to a design of the component.

3.7 Claims 14-15: Providing the support implant with a recess is obvious to a person skilled in the art.

3.8 Claims 17-19: Applying the features of claims 13-15 to a replacement implant does not constitute an inventive step.

3.9 Therefore, the subject matter of claims 4, 14, 15 and 17-19 is not inventive (PCT Article 33(3)).

4 Novelty of claims 1-6 and 13-16 in respect of D3

4.1 Claims 1-6: Document D3 discloses, in figures 6 and 7, a T-shaped base component (detector 11), a sensor (capacity pressure cell), a telemetry device (data-transmitting coil and conductive energy-receiving coil), a connection between these (see cables in figure 6) and assembly means (cylindrical sleeve

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191, internal threads 192).

4.2 Claims 13-16: The "cylindrical sleeve 191" (figure 7) is fitted in the bone and can therefore be regarded as a support implant. It has an internal thread section (internal threads 192).

4.3 Therefore, the subject matter of these claims is not novel (PCT Article 33(2)).

5 Novelty of claims 1, 2, 4-6, 13-15 in respect of D4

5.1 Claims 1, 2, 4-6: Document D4 discloses, in figures 6 and 8, a T-shaped base component (probe 12), a sensor (sensor 16), and a telemetry device (electronic case 42, probe coil 20). The connection between these is disclosed in figure 7. The "body 48" represents an assembly means.

5.2 Claims 13-15: The "burr hole ring 54" can be regarded as a support implant.

5.3 Therefore, the subject matter of these claims is not novel (PCT Article 33(2)).

6 Novelty of claims 1-3 in respect of D5

6.1 Claims 1-3: Document D5 discloses, in figures 1 and 7 and column 11, lines 53-67, a base component (drug delivery system / ball aggregation 700), a sensor (sensor 702) and a telemetry device (transmitter 708). The connection between them is implicit. The

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"screw 710" represents an assembly means.

- 6.2 Therefore, the subject matter of these claims is not novel (PCT Article 33(2)).

GROUP 2

- 7 Novelty of claims 1 and 7-12 and of claims 13-15 in respect of D6

7.1 Claim 1:

The present application does not meet the requirements of PCT Article 33(1), because the subject matter of claim 1 is not novel within the meaning of PCT Article 33(2).

Document D6 discloses a component (see title of D6) suitable for arranging on an implant, with:

- a base component (page 6, lines 3-5);
- at least one sensor device (page 6, line 24) which is arranged in the base component and is used to detect a measurement variable and to produce measurement data for the detected measurement variable (page 6, lines 25-28);
- a telemetry device (page 14, line 29) which is arranged in the base component and is used to emit and/or receive data; and
- a data transfer connection (page 7, lines 24-26) which is arranged between the at least one sensor device and the telemetry device (transfer of data between these units is self-evident), said data comprising the measurement data.

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- 7.2 Claim 2: It will be noted that any component or housing can be regarded as an assembly means, because it always permits assembly (e.g. by means of screws or adhesive).
The term "assembly section" does not represent a further restriction of the scope of protection.
- 7.3 Claims 7-12: D6 discloses a receiving space (reservoir, page 15, line 31) and a pump device (page 15, line 32) that are controlled by the control unit (page 18, lines 13-15).
- 7.4 Therefore, the subject matter of these claims is not novel (PCT Article 33(2)).
- 8 Claims 1 and 7-12 are also not novel (PCT Article 33(2)) over D7, which discloses:
- a base component (body of controller chip 14)
 - sensors (sensor 6)
 - telemetry device (emit and receive unit 16)
 - a transfer connection (22)
 - assembly means (14, see also under 7.1)
 - a receiving space (figure 4: reservoir 34)
 - a pump (figure 4: pump 32)
 - the latter being controlled by a control unit (see figure 1 and paragraph [067]).
- 9 Claims 1, 13 and 17 are also not novel (PCT Article 33(2)) over D8, which discloses in figure 7a:
- a base component (controller body 201, sleeves 62 and 63)

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- sensors (column 7, line 66)
- telemetry device (column 7, line 36)
- a transfer connection (implicit).

The device forms a support implant in the sense that it supports the physical function of the tendon.

It is also a replacement implant, since it replaces the tendon.

Note: The expression "in particular" does not restrict the scope of protection.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box IV

- 1 This international application contains multiple inventions or groups of inventions that are not linked by a single general inventive concept (PCT Rule 13.1), namely:

Group 1: claims 1-6, 13-20
Component with assembly means

Group 2: claims 1,7-20
Component part for dispensing an active substance

- 2 These groups are linked by the features of claim 1. However, the subject matter of claim 1 is not novel over the prior art (see Box V).

- 3 These groups also address different problems, namely:

1. Simple assembly of the component on an implant
2. Dispensing of a therapeutic active substance

- 4 Therefore, these inventions/groups of inventions are not so linked as to form a single general inventive concept (PCT Rule 13.1).